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EXAMINER

MEHTA, PARIKHA SOLANKI

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3737

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05/28/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/602,345	Applicant(s) ZULUAGA ET AL.	
	Examiner PARIKHA S. MEHTA	Art Unit 3737	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 28 January 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-5, 7-13, 20, 21, 43, 44, 46-51 and 56-61 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-5, 7-13, 20-21, 43-44, 46-51 and 56-61 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

Response to Arguments

1. Applicant's arguments with respect to claims 1-5, 7-13, 20-21, 43-44, 46-51 and 56-61 have been considered but are moot in view of the new ground(s) of rejection.

Double Patenting

2. A rejection based on double patenting of the "same invention" type finds its support in the language of 35 U.S.C. 101 which states that "whoever invents or discovers any new and useful process ... may obtain a patent therefor ..." (Emphasis added). Thus, the term "same invention," in this context, means an invention drawn to identical subject matter. See *Miller v. Eagle Mfg. Co.*, 151 U.S. 186 (1894); *In re Ockert*, 245 F.2d 467, 114 USPQ 330 (CCPA 1957); and *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970).

A statutory type (35 U.S.C. 101) double patenting rejection can be overcome by canceling or amending the conflicting claims so they are no longer coextensive in scope. The filing of a terminal disclaimer cannot overcome a double patenting rejection based upon 35 U.S.C. 101.

3. Claims 1 and 10-13 provisionally rejected under 35 U.S.C. 101 as claiming the same invention as that of claims 1, 10, 11, 17 and 18 of copending Application No. 10/940,468. This is a provisional double patenting rejection since the conflicting claims have not in fact been patented.

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. Claims 1, 2, 5, 7-10, 11, 20, 21, 43, 44, 46-49, and 56-61 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hayes et al (US Patent No. 4,967,745), hereinafter Hayes ('745), previously made of record, in view of Bures (US Patent No. 3,865,118), hereinafter Bures ('118).

Regarding claims 1, 2, 5, 7-10, 11, 21 and 46-49, and 56-61, Hayes ('745) teaches a method and apparatus for spectroscopic analysis of plaque within a blood vessel comprising a probe with one or

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more optical fibers extending therethrough, an optical shield and lens configured to contact the intraluminal wall at a point at which light exits the coupler and enters the wall, and a light source and detector in optical communication with the optical fiber (Fig. 1, col. 4 lines 40-51 & 59-64). Hayes ('745) shows the probe to have a rounded distal tip and further states that it may be "hemispherical, flat, lens-shaped, or of any other shape" (col. 7 lines 65-68). The hemispherical tip of Hayes ('745) is considered "atraumatic" as claimed in the instant application, as it is free of any sharp edges, corners, or any other such protrusions that might be reasonably capable of damaging the vessel wall. The rounded tip and transparent optical shield taught by Hayes ('745) together constitute both "an atraumatic light-coupler in contact with the optical fiber, the coupler being configured to atraumatically contact the intraluminal wall at a point at which light exits the atraumatic light-coupler and enter the wall" and a jacket enclosing the fiber as claimed in the instant application. According to this interpretation, a surface of the light coupler is disposed along a side of the probe as recited in claim 59. Hayes ('745) further teaches deflection wires for causing the distal end of the catheter to curve (Figs. 17A-D), which constitutes a probe resiliently assuming a preferred shape as claimed.

Hayes ('745) does not expressly teach that the probe is pre-formed such that, when deployed from the delivery catheter, a natural bend of the probe urges its distal end outward, away from the longitudinal axis of the catheter. In the same problem solving area, Bures ('118) teaches construction of a pre-formed probe that is capable of yielding to the inner shape of a catheter as it is guided towards a target, but after the distal end exits the catheter, it assumes its pre-formed shape that urges the distal tip towards the target tissue in order to achieve reliable and secure contact between the distal tip and the target (col. 3 lines 31-54); in other words, the probe is configured to have a flexible shape memory. It would have been obvious to one of ordinary skill in the art at the time of invention to modify the probe of Hayes ('745) to incorporate these flexible shape memory features of Bures ('118), in view of the teachings of Bures ('118).

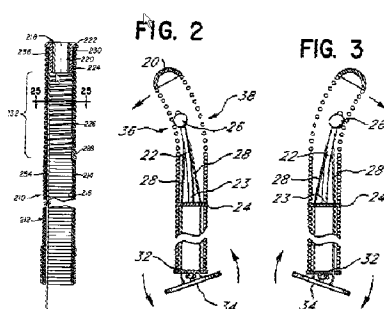
Regarding claim 20, Hayes ('745) specifically provides the probe for use with a laser source (col. 7 lines 50-64), and further defines "laser" as a device that produces infrared light (col. 1 lines 17-23).

Regarding claims 21, 43 and 44, Hayes ('745) additionally teaches means and steps for providing the received light to a computer (col. 21 lines 14-21), wherein the computer constitutes a processor as claimed in the instant application.

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6. Claim 3 is rejected under 35 U.S.C. 103(a) as being unpatentable over Hayes ('745) in view of Bures ('118), further in view of Hammerslag (US Patent No. 5,372,587), hereinafter Hammerslag ('587), previously made of record.

Hayes ('745) and Bures ('118) substantially teach all features of the present invention as previously discussed for claim 1. Hayes ('745) and Bures ('118) do not teach a jacket comprised of wound coil-wire. In the same field of endeavor, Hammerslag ('587) teaches the use of a coiled wire sheath in conjunction with catheters, cannulae, guidewires and the like for the purpose of enhancing steerability of such medical devices (col 1 line 14, Figure 1).

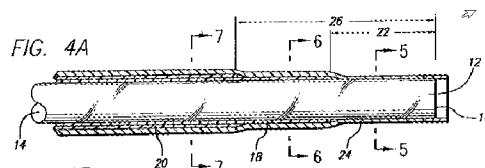


Source: Hammerslag ('587) Figures 1-3

It would have been obvious to one of ordinary skill at the time of invention to modify the probe of Hayes ('745) to further include the wound coil-wire jacket of Hammerslag ('587) to facilitate and improve ease of navigation of the probe through the patient's vasculature, in view of the teachings of Hammerslag ('587).

7. Claim 4 is rejected under 35 U.S.C. 103(a) as being unpatentable over Hayes ('745) in view of Bures ('118) and Hammerslag ('587) as applied to claim 3 above, and further in view of Derbin (US Patent No. 6,562,021), hereinafter Derbin ('021), previously made of record.

Hayes ('745), Bures ('118) and Hammerslag ('587) substantially teach all features of the present invention as previously discussed for claim 3. Neither Hayes ('745), Bures ('118) nor Hammerslag ('587) teach that the coil wire of the probe jacket is of variable diameter. In the same field of endeavor, Derbin ('021) teaches the use of a variable-thickness catheter shaft in order to provide variations in stiffness along the length of the catheter, more specifically to make the distal tip more flexible than the rest of the body (Fig 4A).



Source: Derbin ('021) Figure 4a

It would have been obvious to one of ordinary skill in the art at the time of invention to modify the probe of Hayes ('745), previously modified by Hammerslag ('587), to further include a variable-diameter coil-wound jacket so as to improve distal flexibility while also maintaining proximal stiffness during probe navigation, in view of the teachings of Derbin ('021).

8. Claims 12, 13, 50 and 51 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hayes ('745) in view of Bures ('118), further in view of Utzinger et al (Fiber optic probes for biomedical optical spectroscopy. *Journal of Biomedical Optics*. 8(1): pp. 121-147. January 2003), hereinafter Utzinger (2003), previously made of record.

Hayes ('745) and Bures ('118) substantially teach all features of the present invention as previously discussed for claim 1. Hayes ('745) and Bures ('118) do not expressly teach an embodiment of the probe wherein the coupler is integral with the optical fiber. In the same field of endeavor, Utzinger (2003) teaches that cleaving and polishing the distal end of an optical fiber to create a beveled or flat end surface creates a coupling surface that is more efficient than a lens coupler (p. 123 ¶ 3). It would have been obvious to one of ordinary skill in the art at the time of invention to modify the probe of Hayes ('745) to omit the separate lens coupler and instead use a cleaved, polished distal end of the optical fiber as the light coupler in order to enhance the coupling efficiency of the probe, in view of the teachings of Utzinger (2003).

Conclusion

9. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH

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shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to PARIKHA S. MEHTA whose telephone number is (571)272-3248. The examiner can normally be reached on M-F, 8 - 4:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brian Casler can be reached on 571.272.4956. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Brian L Casler/

Supervisory Patent Examiner, Art Unit
3737

/Parikha S Mehta/

Examiner, Art Unit 3737